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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,171	06/27/2003	Daniel D. Auger	DEP754NP	7798
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PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER HOFFMAN, MARY C	
			ART UNIT 3733	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/19/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/609,171

Applicant(s)

AUGER ET AL.

Examiner

Mary Hoffman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 and 4 is/are allowed.
- 6) ☒ Claim(s) 1 and 5-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/27/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02/01/2007.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/01/2007 has been entered.

Claim Objections

Claims 5-14 are objected to because of the following informalities:

In claim 1, lines 22, 24, and 27, Applicant recites "guide arm" and this should be changed to --guide arm portion-- to be consistent in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 5-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 recites the limitation "the planar contact surface of the shim arm" in lines 21, 23, and 26. It is not clear if this limitation refers to the planar contact surface for contacting part of the guide arm recited in line 17, the planar surface for contacting part of one of the bones of the knee recited in line 18, or a different, newly recited planar surface. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-6, 10 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by White (U.S. Patent No. 5,662,656).

White discloses a kit (see FIG. 1) for locating a distal femoral resection plane in uni-compartmental knee surgery, the kit comprising: a shim including a shim arm (ref. #25) and a mounting member (ref. #85,87) connected to the shim arm; and a combination cutting and spacer guide including a cutting block portion (ref. #113) and a guide arm portion (ref. #79), the cutting block portion having an anterior side and a posterior side and surfaces defining a cutting guide slot (ref. #117) extending from the anterior side to the posterior side, the cutting guide slot lying in a plane defining the distal femoral resection plane, the guide arm portion having a posterior end spaced from the cutting block portion, a planar femoral surface extending outward from the posterior

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side of the cutting block portion to the posterior end, and a planar tibial surface extending from the cutting block portion outward to the posterior end, the planar femoral surface lying in a plane spaced from the plane of the planar tibial surface, the planes of the tibial surface and femoral surface being substantially parallel to and spaced from the distal femoral resection plane of the cutting guide slot; the combination cutting and spacer guide having a shim mounting opening; wherein the shim arm has a planar contact surface for contacting part of the guide arm (ref. # 53) and a planar contact surface for contacting part of one of the bones of the knee (ref. #31), the mounting member being sized and shaped to be receivable within the mounting opening of the combination cutting and spacer guide to removably mount the shim to the guide arm. The shim comprises a femoral shim and wherein the arm of the femoral shim has a surface area substantially the same as the surface area of the femoral surface of the guide arm of the combination cutting and spacer guide. The cutting block portion is removably mountable to the femur. The cutting block portion includes a plurality of holes (ref. #133,143) extending from the anterior side to the posterior side for mounting the combination cutting and spacer guide to the femur, the kit further comprising anchoring members (ref. #129) receivable within the holes in the cutting block portion and a cutting member receivable within the cutting guide slot. The guide arm and shim are sized to be received on a single side of the tibia. The shim mounting opening of the combination cutting and spacer guide comprises an elongate slot extending from the medial to the lateral side of the guide arm. The guide arm comprises a pair of spaced parallel plates.

Claims 1, 5 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Fargie et al. (U.S. Patent No. 4,736,737).

Fargie et al. a kit for locating a distal femoral resection plane in uni-compartmental knee surgery, the kit comprising: a shim including a shim arm (ref. #30) and a mounting member (ref. #28) connected to the shim arm; and a combination cutting and spacer guide including a cutting block portion (ref. #12) and a guide arm portion (ref. #38), the cutting block portion having an anterior side and a posterior side and surfaces defining a cutting guide slot (ref. #44) extending from the anterior side to the posterior side, the cutting guide slot lying in a plane defining the distal femoral resection plane, the guide arm portion having a posterior end spaced from the cutting block portion, a planar femoral surface extending outward from the posterior side of the cutting block portion to the posterior end, and a planar tibial surface extending from the cutting block portion outward to the posterior end, the planar femoral surface lying in a plane spaced from the plane of the planar tibial surface, the planes of the tibial surface and femoral surface being substantially parallel to and spaced from the distal femoral resection plane of the cutting guide slot; the combination cutting and spacer guide having a shim mounting opening (holes in which ref. #28 are received); wherein the shim arm has a planar contact surface for contacting part of the guide arm and a planar contact surface for contacting part of one of the bones of the knee, the mounting member being sized and shaped to be receivable within the mounting opening of the combination cutting and spacer guide to removably mount the shim to the guide arm. The cutting block portion is removably mountable to the femur. The cutting block portion

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and the guide arm portion are integral. The cutting block portion has a bottom surface co-planar with the tibial surface of the guide arm. The guide arm and shim are sized to be received on a single side of the tibia.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-8 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over White (U.S. Patent No. 5,662,656).

White discloses the claimed invention except for the pair of spaced parallel plates being integral with the cutting block portion, and the cutting block portion and the guide arm portion are integral, and a tibial surface of the guide arm having a maximum medial-lateral dimension of 32 mm and a maximum anterior-posterior dimension of 57 mm, the combination cutting and spacer guide having a maximum anterior-posterior dimension along the tibial surface of the distal side of the cutting block portion and the tibial surface of the guide arm of 67 mm, and the femoral surface of the guide arm having a maximum medial-lateral dimension of 17 mm and a maximum anterior-posterior dimension of 47mm.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of White with the pair of spaced parallel

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plates being integral with the cutting block portion, and the cutting block portion and the guide arm portion are integral, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

It would have further been obvious to one having ordinary skill in the art at the time the invention was made to construct the kit for locating a distal femoral resection plane of White with a tibial surface of the guide arm having a maximum medial-lateral dimension of 32 mm and a maximum anterior-posterior dimension of 57 mm, the combination cutting and spacer guide having a maximum anterior-posterior dimension along the tibial surface of the distal side of the cutting block portion and the tibial surface of the guide arm of 67 mm, and the femoral surface of the guide arm having a maximum medial-lateral dimension of 17 mm and a maximum anterior-posterior dimension of 47mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fargie et al. (U.S. Patent No. 4,736,737).

Fargie et al. discloses the claimed invention except for the tibial surface of the guide arm having a maximum medial-lateral dimension of 32 mm and a maximum anterior-posterior dimension of 57 mm, the combination cutting and spacer guide having a maximum anterior-posterior dimension along the tibial surface of the distal side of the cutting block portion and the tibial surface of the guide arm of 67 mm, and the femoral

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surface of the guide arm having a maximum medial-lateral dimension of 17 mm and a maximum anterior-posterior dimension of 47mm.

It would have further been obvious to one having ordinary skill in the art at the time the invention was made to construct the kit for locating a distal femoral resection plane of Fargie et al. with a tibial surface of the guide arm having a maximum medial-lateral dimension of 32 mm and a maximum anterior-posterior dimension of 57 mm, the combination cutting and spacer guide having a maximum anterior-posterior dimension along the tibial surface of the distal side of the cutting block portion and the tibial surface of the guide arm of 67 mm, and the femoral surface of the guide arm having a maximum medial-lateral dimension of 17 mm and a maximum anterior-posterior dimension of 47mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Allowable Subject Matter

Claims 3 and 4 are allowed.

Response to Arguments

Applicant's arguments filed 02/01/2007 have been fully considered but they are not persuasive.

In response to Applicant's argument that the White and Fargie references do not anticipate the claim limitations including the recitations "...when the shim is mounted the guide arm..." it is noted that these are recitations of intended use. The devices of White

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and Fargie are capable of, while in their disassembled states (see FIG. 1), being “mounted” in such a way to meet Applicant’s current claim language. The term “mounted” can be interpreted as two components merely being fixed securely together, or put into contact, and does not necessarily require that the component be fixed together in any particular fashion or in their intended final configurations. With regard to this statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the cited prior art references, which are capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Furthermore, the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Moreover, the new claim recitations are unclear, since there appears to be a 35 U.S.C. 112, 2nd paragraph indefiniteness issue due to a lack of antecedent basis in claim 1 (see 112, 2nd paragraph rejection above).

In response to Applicant’s argument that the White reference teaches away from having components 113 and 25 be integral, the examiner respectfully disagrees. Although the examiner agrees that the White device discloses a multi-component device that can be used for multiple resections, the examiner does not consider White

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to "teach away" from integral devices. Rather, White discloses advantages to using multi-piece components, i.e. only one guide is needed for both anterior and distal femoral resection. Although less advantageous because it would require the need for two separate guides, a device containing integral components 113 and 25 would still be able to perform the device's intended use and the function of the White device would not be destroyed.

The rejections are deemed proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



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